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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/006,400

11/30/2001

Richard S. Ginn

16497.8.3.2.1

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04/02/2008

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

04/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/006,400	Applicant(s) GINN, RICHARD S.	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75 and 80-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75 and 80-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/11/2007, 10/10/2007, 10/30/2007, 01/31/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 80 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 80 is identical to claim 12 therefore it is failing to further limit claim 11.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 60 recites the limitation "the deploying step" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11-16, 21-25, 27-32, 38-42, 46-49, 51, 54-56, 60-75, and 80-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. (5,853,421) in view of Ginn, et al. (6,626,918), or Ginn, et al. (6,391,048).

7. Regarding the apparatus claims:

Claims 11, 12, 16, 21, 22, 63, 67, 80, 85, and 89:

Leschinsky discloses an apparatus for positioning a closure device within a passage, comprising: an elongate member (combination of components 66 and 54) comprising a proximal end, a distal end, and a lumen extending between the proximal and distal ends defining a longitudinal axis (Fig. 1-13); a closure element (68) deliverable from the elongate member (combination of components 66 and 54) for sealing the passage (Fig. 16-18); and a selectively expandable locator member (14, 214), extending through the lumen (Fig. 14-16), the locator member (14, 214) comprising a distal portion (22 which extends from the loop (24) formed by the locator member) extending distally beyond the distal end of the elongate member (combination of components 66 and 54) (Fig. 14-16), the distal portion (22) comprising an elongate deflectable element (the distal portion deflects to form a J-shape end (16) as well as a loop (24) at the distal end) comprising a helically wound wire (14, 214 is a helical wound wire as disclosed in Col. 5 Line 16 and Col. 10 Lines 59-60) extending between a proximal end and a distal end, and having an intermediate portion therebetween (Fig. 1-3, 5, and 28-29), and a control element (12, 212, 228, 238) coupled to the deflectable element and passing through at least one coil of the helical wound wire (Fig. 1-3, 5, 28-29 where the control element is inside the helical wound coil and the control element is

connected to the distal end of the deflectable member as seen in the figures), the control element being movable axially for causing an intermediate portion of the deflectable element to buckle substantially transversely with respect to the longitudinal axis (Fig. 1-3 and 28-29 where the deflectable element forms a loop (24)) (Col. 11 Lines 45-47).

Furthermore Leschinsky discloses that the control element (12, 212, 228, 238) comprises a tether (the control element is a tether) extending along an outer surface of at least the intermediate portion of the helically wound wire (Fig. 28); a housing (73, 58) slidably coupled to the elongate member (combination of components 66 and 54) (Fig. 11-13), the housing configured for releasably holding a closure element (68) (the housing is holding the closure element inside the elongated member in order to prevent it from being deployed accidentally, Fig. 10 where the closure element is being held inside the elongated member which is inside the housing 58); that at least a portion of the helically wound wire communicates with the body lumen when the helically wound wire is in the transversely expanded configuration (Fig. 6-7).

Leschinsky discloses the claimed invention disclosed above with the exception of the closure element being a clip instead of it being a fluid sealant. However, each of the other cited references disclose the use of clips to close vascular punctures, and the two Ginn references disclose that it was known to either supplement a clip closure with a sealant, or that a clip is a known alternative to the use of a sealant in closing vessel puncture wounds. Therefore, it would have been obvious to have either exchanged the closure sealant with a clip applying device as is taught by the cited teaching references,

or to add a clip applying device in combination with the sealant, as this has been shown to be an effective alternative to sealant alone in the sealing of vessel puncture wounds.

Claims 13 and 64: Leschinsky discloses a deflectable element which forms in the same manner as the deflectable element of the applicant therefore if the applicant deflectable element at the intermediate portion has a cross-section in its buckled configuration that is larger than a cross-section of the distal portion, Leschinsky's deflectable element would have the same structure.

Claims 14 and 65: Leschinsky discloses that the apparatus further comprising an actuator (244) on a proximal end of the elongate member (Fig. 15 and 29, where the actuator is at the proximal end of the locator member (Fig. 29) which in use extends through the elongated member (Fig. 15 where element 10 is the assembly of one of the embodiments which include the locator element)), the actuator (244) coupled to the locator member (14, 214) (Fig. 29), the actuator configured for moving the control element (12, 212, 228, 238) proximally for buckling the intermediate portion of the deflectable element (Col. 11 Lines 45-47)/ The force is applied by the operator at the proximal end of the device where the actuator (244) is located and by bucking the control element is moved proximally.

Claims 15, 23, and 66: Leschinsky discloses that the elongate member (combination of components 66 and 54) and the selectively expandable locator member (14, 214) comprise cooperating detents (the loop (24) forms a detent at the distal end which does not allow that the locator member passes from a certain location through the lumen (second detent) of the expandable member) for substantially securing the selectively

expandable locator member axially with respect to the elongate member when the selectively expandable locator member is fully inserted into the elongate member.

Claim 24: Leschinsky discloses that the apparatus further comprising an actuator (74) coupled to the housing (72) (Fig. 11-13), the actuator configured for advancing the housing distally to deploy a closure element therefrom (Col. 7 Lines (10-15). As the actuator (74) is pushed the housing is inserted closer to component 58 which allows for the closure element to be released.

Claim 25: Leschinsky discloses that the apparatus further comprising a closure element (68) located within the housing (58) (Fig. 10 where the closure element is being held inside the elongated member which is inside the housing 58).

8. Regarding the method claims:

Claims 27- 29, 32, 38-40, 46, 47, 51, 54, 56, 60, 68-70, 73, 81-84, 86-88, and 90:

Leschinsky discloses a method for sealing a passage communicating with a body lumen using an elongate member (combination of components 66 and 54) comprising proximal and distal ends, and a closure element (68) deployable from the distal end of the elongate member (Fig. 16-18), the method comprising: providing a selectively expandable locator member (14, 214) coupled to the elongate member (combination of components 66 and 54) such that a distal portion 22 which extends from the loop (24) formed by the locator member) extending distally beyond the distal end of the elongate member (combination of components 66 and 54) (Fig. 14-16); advancing the distal end of the elongate member (combination of components 66 and 54) through a patient's skin towards the body lumen via the passage until the distal portion of the locator member is

located within the body lumen (Fig. 14-18); moving a control element (12, 212, 228, 238) coupled to a deflectable element (the distal portion deflects to form a J-shape end (16) as well as a loop (24) at the distal end) to buckle the deflectable element on the distal portion of the selectively expandable locator member from an axial collapsed configuration to a transverse expanded configuration (Fig. 1-3, 5, and 28-29 where the deflectable element forms a loop (24)) (Col. 11 Lines 45-47), the deflectable element comprising a helically wound wire (14, 214 is a helical wound wire as disclosed in Col. 5 Line 16 and Col. 10 Lines 59-60) extending between a proximal end and a distal end and having an intermediate portion therebetween (Fig. 1-3, 5, and 28-29) and the control element (12, 212, 228, 238) passing through at least one coil of the helical wound wire (Fig. 1-3, 5, 28-29 where the control element is inside the helical wound coil and the control element is connected to the distal end of the deflectable member as seen in the figures); manipulating the elongate member until the deflectable element in the expanded configuration contacts a proximal wall of the body lumen (Fig. 5-8), thereby providing a tactile indication of a location of the distal end of the elongate member relative to the body lumen (Fig. 5-16 and Col. 6 Lines 44-49); and deploying the closure element (68) from the distal end of the elongate member (combination of components 66 and 54) within the passage (Fig. 16-18).

Additionally, Leschinsky discloses that the method further comprising withdrawing the elongate member and the selectively expandable locator member from the passage, leaving the closure element to substantially close the opening (Fig. 17-18); an introducing sheath (54) introduced into the body lumen (Fig. 7) and that more than

one instrument can be introduced through the lumen of the sheath (the member (66) and the locator member (14, 214) are introduced into the lumen through the sheath as well as the dilator (56)) (Fig. 7-15); that the housing (72, 58) is movable between a proximal position (Fig. 11-13) and a distal position (Fig. 14-16), the distal position being a predetermined distance from the deflectable element in its expanded configuration (Col. 6 Lines 44-49 and Col. 7 Lines 15-18); the step of advancing a closure element comprises advancing a housing (72, 58) along the elongate member (Fig. 10, 15, and 16) until the closure element (68) reaches the predetermined location (15-17).

Also refer to the rejections performed on the apparatus on the first part of this rejection.

Leschinsky discloses the claimed invention disclosed above with the exception of the closure element being a clip instead of it being a fluid sealant. However, each of the other cited references disclose the use of clips to close vascular punctures, and the two Ginn references disclose that it was known to either supplement a clip closure with a sealant, or that a clip is a known alternative to the use of a sealant in closing vessel puncture wounds. Furthermore, the clip disclosed by Ginn (6,626,918) has tines (874) which penetrate the tissue when deployed.

Therefore, it would have been obvious to have either exchanged the closure sealant with a clip applying device as is taught by the cited teaching references, or to add a clip applying device in combination with the sealant, as this has been shown to be an effective alternative to sealant alone in the sealing of vessel puncture wounds.

Claims 30, 31, 71, 72: Leschinsky discloses that the body lumen comprises a blood vessel (44), and wherein the procedure comprises the delivery of a therapeutic agent (collagen is being used which is a therapeutic element).

Claim 41: Leschinsky discloses that the selectively expandable locator member (14, 214) is introduced into the lumen of the tubular member before the distal end of the tubular member (combination of components 66 and 54) is advanced into the passage such that the distal portion of the selectively expandable locator member is advanced through the passage into the body lumen as the distal end of the tubular member is located into the passage (Fig. 5-6).

Claim 42: Leschinsky discloses that the selectively expandable locator member (14, 214) introduced into the lumen of the tubular member (combination of components 66 and 54) after the distal end of the tubular member is advanced into the passage (Fig. 10). Once the distal tip of the tubular member (54) is introduced into the passageway it is then advanced forward where the locator member is inserted into the tubular member's lumen.

Claims 48 and 49: Leschinsky discloses that the step of introducing the selectively expandable locator member comprises: disposing a tubular member (46) through a patient's skin into the passage until a distal end of the tubular member is disposed proximate the body lumen (Fig. 4); introducing the selectively expandable locator member (14, 214) into a lumen of the tubular member until the distal portion of the locator member extends beyond the distal end of the tubular member into the body

lumen (Fig. 5); withdrawing the tubular member from the passage before advancing a closure element into the passage (Fig. 6-7).

Claim 55: Leschinsky discloses that the cooperating elements comprise a marker (28, 28') on the selectively expandable locator member (14, 214) (Fig. 6) having a predetermined relationship (distance D) with the distal portion of the selectively expandable locator member (Col. 5 Lines 30-33).

Claim 61: Leschinsky discloses that the deflectable element is collapsed during the deployment step (Fig. 6). The deflectable element is inserted into the lumen in a collapsed state (the device is straight), once the deflectable member hits/attaches to the vessel wall it bends therefore the state in which it is inserted (Fig. 5) is interpreted as collapsed.

Claim 62: Leschinsky discloses that the elongate member (combination of components 66 and 54) comprises a tubular member (54), and wherein the distal portion of the selectively expandable locator member (14, 214) is retracted into the lumen after the deflectable element is collapsed (Fig 16-17).

Claim 74: Leschinsky discloses that the deploying step comprises advancing a housing (58) distally along an exterior of the elongate member (66) (Fig. 10 where the housing can be moved distally along the elongated member), the housing (58) having the closure element (68) detachably held thereto (the closure element (68) is held inside the elongated member therefore one the elongated member is inside the housing so will the closure element).

Claim 75: Leschinsky discloses that the housing (58) is movable between a proximal position and a distal position (the housing can be moved distally or proximally since the device needs to be removed from the body), the distal position being a predetermined distance from the deflectable element in its expanded configuration (Col. 6 Lines 44-49 and Col. 7 Lines 15-18).

9. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. (5,853,421) in view of Ginn, et al. (6,626,918), or Ginn, et al. (6,391,048) in further view of Janzen (5,437,631).

Leschinsky in view of Ginn(s) teaches all the claimed limitations discussed above except for the step of introducing one or more instruments through the lumen of the tubular member into the body lumen prior to performing the closure of the blood vessel. However, Janzen discloses that introducing one or more instruments through the lumen of the tubular member (32) into the body lumen prior to performing the closure of the blood vessel (Fig. 2 and Col. 5 Lines 26-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Leschinsky in view of Ginn(s) with one or more instruments inserted into the lumen of the tubular member in view of the teachings of Janzen, since it is known in the art to use other medical devices inserted through a tubular member.

Response to Arguments

10. Applicant's arguments, see section IV in pages 24-25, filed on July 19, 2007, with respect to the rejection(s) of claim(s) 11, 14-16, 21, 23-25, 27-32, 38, 42, 54-56, 60-62,

68-75, 85-88, and 90 under 35 U.S.C. §103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference which has the limitations of the amended independent claims as well as the dependent claims as can be seen in the rejection above.

11. Applicant's arguments, see section IV in pages 25, filed on July 19, 2007, with respect to the rejection(s) of claim(s) 63-67 and 89 under 35 U.S.C. §103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference which has the limitations of the above mentioned claims as can be seen in the rejection above.

12. Regarding claims 12, 13, 22, and 80-84 which were indicated as having allowable subject matter if rewritten in the independent form on the office action mailed on April 7, 2007; those claims have been regrettably withdrawn by the examiner due to newly found prior art reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Darwin P. Erezol/
Primary Examiner, Art Unit 3773